EVALUATION OF POST – EXTRACTION BLEEDING CONTROL BY HAEMOSTATIC AGENT COATED GAUZE VERSUS STANDARD GAUZE IN DENTAL EXTRACTION CASES – AN INVIVO STUDY

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CERTIFICATE

This is to certify that the dissertation entitled **"EVALUATION OF POST - EXTRACTION BLEEDING CONTROL BY HAEMOSTATIC AGENT COATED GAUZE VERSUS STANDARD GAUZE IN DENTAL EXTRACTION CASES – AN INVIVO STUDY"** is a bonafide research work done by Dr. A. THINAKAR BABU, Post Graduate student during the period of 2012 – 2015 under my guidance and supervision. This dissertation is submitted to the Tamil Nadu Dr. M.G.R. Medical University, Chennai in partial fulfillment of the requirements for the award of Master of Dental Surgery, Branch III (Oral and Maxillofacial surgery). It has not been submitted (partially or fully) for the award of any other degree or diploma.

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LIST OF ABBREVIATION

SPSS	-	Statistical Package for Social Sciences
ASD	-	Alveolitis Sicca Dolorosa
PTFE	-	Poly Tetra Fluro Ethylene
HDD	-	Hemocon Dental Dressing
CA	-	Celox-A
CG	-	Compact Gauze
CF	-	Chito Flex
WS	-	Wound Stat
SG	-	Standard Gauze
eptfe	-	Expanded Poly Fluro Ethylene
UK	-	United Kingdom
BCSH	-	British Committee for Standards in Hematology
BDA	-	British Dental Association
NPSA	-	National Patient Safety Agency
ASA	-	Acetyl Salicylic Acid
Cox-1	-	Cyclo Oxygenase
CDSCO	-	Central Drug Standard Control Organization
PHC	-	Primary Health Centre

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Abstract

ABSTRACT

Background:-

Bleeding is more common problem encountered by surgeons of various specialities. Different types of bleeding control methods are available around the world for different types of surgery. Various haemostatic agents are available for different types of surgery. One haemostatic agent that is used in Neurosurgery may not be applicable to maxillofacial surgery and vice versa. So in order to find a haemostatic agent that is used in dental extraction cases that should be of antimicrobial, antihygroscopic, better handling property at the same time with risk benefit and cost benefit ratios simultaneously with no systemic absorption, only one haemostatic agent is presently available in the Indian market.

Objectives:

The present study was undertaken to evaluate the post extraction bleeding control by Feracrylum (haemostatic) agent coated gauze versus standard gauze (10 x 10 cm) in dental extraction cases. This study also investigate the efficacy of Feracrylum over gauze in post extraction wound healing and antimicrobial (antibacterial & antifungal) property.

Methods:

Ten patients were included in the study. Feracrylum coated gauze and standard gauze of 10x10cms is used in group I and group II patients. The patients were referred from the various departments for therapeutic dental extraction. Extraction of teeth in the right upper guardant is compared with extraction of teeth in the left upper guardant or extraction of teeth in the right upper guardant is

compared with extraction of teeth in the right lower guardant and vice versa. Group I patients after extraction was placed with gauze of 10 x 10 cms over extraction socket and checked for bleeding control at 2 minutes and at 5 minutes. Group II patients after extraction was placed with Feracrylum Haemostatic agent coated gauze in the extraction socket and bleeding was noted at 2 minutes and at 5 minutes.

Results:

The results showed a statistically significant difference in the outcome of bleeding control between two groups and the patients with Feracrylum coated gauze responded to the procedure well. Post extraction wound healing is also better among the Feracrylum coated gauze administered patients. There was no difficulty in control of bleeding encountered in both the groups.

Conclusion

It may be concluded that Feracrylum gives better results in patients with respect to control of bleeding. Standard gauze also control bleeding but at a later time than Feracrylum administration. Regarding past extraction wound healing, antibacterial and antifungal properties with no systemic absorption along with risk benefit, cost benefit and better handling property, Feracrylum is the drug of choice for haemostatic action in dental extraction cases.

Introduction

To be aware of the process of hemostasis and thrombosis is decisive to the treatment and stabilization of a patient undergoing surgical procedure.

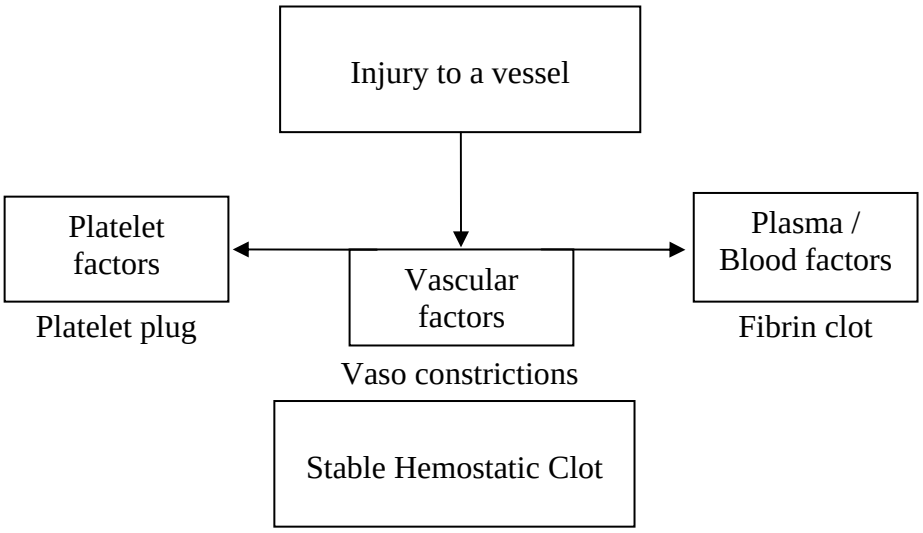
"Hemostasis" shortly denotes "the Arrest of bleeding". Hemostasis is more than that

In Surgery hemostasis is about

- bleeding
- clotting
- timing
- balance between bleeding and clotting.

Hemostasis can be defined as "a tightly regulated process that maintain the blood flow through the vasculature simultaneously as a thrombotic response to tissue damage occurs."

Maintaining hemostasis requires a complex interaction of vessel wall. Platlets, coagulation and fibrinolytic systems.



The synergy of factors that contribute to normal hemostasis[1].

There are two stages of hemostasis: Primary and secondary. Primary hemostasis begins suddenly after endothelial disruption and involves vasoconstriction, platelet factors and formation of soft aggregate plug. During secondary hemostasis soft plat let plug is stabilized to form a clot.

Then a coagulation cascade starts with a series of dependent reactions and finally thrombin converts a soluble plasma protein fibronogen to insoluble protein fibrin and the conversion of factor XIII to factor XIIIa. This factor along with calcium stabilizes the fibrin and results in cross linkage of the fibrin monomers, producing a stable clot.[1]

During in dental extraction procedures, it is important to maintain a fine balance between bleeding and clotting, so that blood continues to flow at the extraction site without excessive loss of blood, for optimum surgical outcome.

Alveolar Osteitis is a well known complication after extraction or surgical removal of tooth. The exact etiology of Alveolar osteitis is not well understood. Birn's series of articles gives more information.[2-5] The etiology of (Alveolar osteitis) is increased local fibrinolysis leading to disintegration of clot. The fibrinolysis is the result of plasminogen pathway activation, which can be accomplished via direct (physiologic) or Indirect (non – physiologic) activator substances. In order to avoid alveolar ostetis (dry socket) in future after dental extraction, clot Stabilization is very important. [2-5]

If the clot disintegrates, there is more chance for the extraction site more prone for infection and alveolar osteitis (dry socket).Wound healing is also delayed if there is more loss of blood. Birn suggested antibacterial and antifibrinolytic theory. Both theories are important for to prevent infection and alveolar osteitis.

The following are several advantages of effective haemostasis after extraction. Reduced Procedure (dental extraction) time, decreased morbidity and mortality (may arise), early disposal of cases. Stabilization of the clot.

- The haemostatic agent which we are going to use in this research purpose must be Antifibrinolytic and Antibacterial. Effective hemostasis after extraction can offer various advantages to the patient, surgeon, and health care facility. Surgeons have different options to control bleeding including mechanical, thermal techniques as well as pharmacotherapies and topical agents in minor and major surgeries. The use of this agent (Feracrylum) can be used in surgeries to control bleeding if this agent is satisfied in this research.

The conventional techniques to control surgical bleeding in major surgeries has led to some disadvantages and or might endanger vital structures. They can also produce necrotic areas with increased likelihood of infection and impaired healing. But in this research this is a minor surgical procedures which is performed by every dental surgeon, so there is necessity for a hemostatic agent which satisfies the dental surgeon in every aspect to be used after dental extraction. If a hemostatic agent which controls blood flow to satisfied level, then the confidence level of surgeon in dentistry is adequate to perform extraction.

The ideal hemostatic agent should be easy to use with good risk-benefit and cost-benefit ratios.[7] Such as agent should be easily applicable, highly predictable in creating hemostasis, biocompatible and must not have an side or adverse effect on extraction site and wound healing should have occurred well on that area without any discomfort to the patient'.

Feracrylum is a drug known for arrest of bleeding and it is approved by central drug standard control organization in 2005.As a result it is available in the Indian market and is presently available under various brand names. It is used in humans and it is tried in various surgeries. It is used in hypospadias surgeries for infants and its only indication is being the arrest of bleeding.[7]

Capillary oozing is commonly encountered problem in the branch of oral and maxillofacial surgery. Capillary bleeding can occur during procedures from simple dental extraction and also in major maxillofacial procedures and during maxillofacial reconstruction of damaged parts of the reconstructive areas.

It also cuts off supply of oxygen and nutrients to the surgical site area leading to impaired wound healing and surgical site Infection in the area of interest.

Restoring the capillary branch ensures reduced inflammation fasten wound healing and reduces infection.

Therefore the tissue repair, coagulation and inflammation are closely related. Healing of wound is more complex series of biologic events. [24]

The ability of damaged tissue to reconstruct and repair is a response to life itself.

The healing of wound and all of tissue has an almost identical repair process, but it may be modified due to extrinsic and intrinsic factors.

Constant research is under review to gain knowledge of biologic events and dynamic events sequence behind healing and also to enhance heeling phase.

Aims & Objectives

AIM:

The aim of the study is to evaluate the post extraction bleeding control by haemostatic agent coated gauze vs standard gauze of 10 x 10 cm in dental extraction cases.

OBJECTIVES:

The objectives of this study is to

- Investigate the efficacy of feracrylum haemostatic agent over traditionally used gauze piece in dental extraction
- To compare the difference in arrest of bleeding over standard gauze in dental extraction cases.
- Compare the post extraction wound healing
- To find out antimicrobial and antihygroscopic property of feracrylum over gauze device.

Review of literature

There are several studies in the surgical literature concerning control of blood loss by several haemostatic agent that are relevant to this investigation. Their studies are reviewed below,

Srinath S et al in 2008 reviewed the literature on topical haemostatic Agents in surgery. He stated various advantages and disadvantages of topical haemostatic agent. Passive haemostatic topical agents offer improved blood coagulation by adhering to the bleeding site providing platelet aggregation while reinforcing the fibrin clot. They are useful in situation of uncontrolled bleeding because of their layer absorption capacity and greater mass provided by their more fibrous/ dense structures. Any portion of passive topical haemostatic after retained in the wound that has not participated in the haemostasis will absorb effusion and moisture and expand. Regarding active topical agents, he restated that it had a rapid onset of action, providing haemostasis within ten minutes in most patients. Furthermore, approximately four of every five patients achieved complete haemostasis within two minutes with active topical haemostasis agent compared with only one-third of patients receiving the passive topical haemostasis agents.

Birn et al in 1973 reviewed his study on the etiology and pathogenesis in fibrinolytic alveolitis. He showed that there is increased fibrinolytic activity in dry sockets and activation of plasminogen to plasmin in the presence of tissue activators. He also mentioned that difficulty extraction occur in adult & dense bone which may have a diversed vascularity. He proposed that trauma from extraction and aggressive extraction cause inflammation of the alveolus, osseous medulla which leads to release of cell mediators. This causes fibrinolytic activity.

In the same study he showed that vasoconstriction cause temporary local ischemia which include the risk of developing alveolar osteitis.[2] He studied Bacteria and fibrinolytic activity in dry socket and discovered that plasmin like activity in dry sockets was not present at normal extraction sites.[3] His study of fibrinolytic activity of normal alveolar bone showed that kinases are liberated during inflammation through direct or indirect activation of plasminogen in the blood. These kinasescauses lysis and destruction of blood clot. Tissue or plasma pro-activators and activators convert the plasminogen to fibrin, resulting in the dissolution of the clot by disintegration of fibrin.[4] He dealt with the fibrinolytic activity of alveolar bone in alveolitis sicca dolorosa (ASD) or dry socket. It was shown that 1) alveolar bone in ASD contains stable tissue activators but no labile activators, and 2) alveolar bone in ASD contains free plasmin. These findings were compared with previous investigations of the fibrinolytic activity in normal alveolar bone, and it was concluded that liberation of the tissue activators has taken place in ASD. The importance of this conclusion for the etiology and pathogenesis of ASD were discussed. [5]

Baumann et al in 2013 did a prospective study on the development of suture hole bleeding at peripheral arterial bypass anastomoses using PTFE. Graft prostheses is a common problem in peripheral vascular surgery. The ideal haemostat should be easy to use with good risk benefit and cost-benefit ratios.[6] Such an agent should be easily applied in a controlled fashion, highly predictable in creating haemostasis, nontoxic and must not have an adverse affect on anastomostic patency, increased anastomotic strength would also be beneficial.[6] Traditionally the problem is managed by compression with surgical swabs and reversal heparin or by using

several haemostatic device (e.g. different forms of collagen, oxidized cellulose, gelatine sponge, ethylcyanoacrylate glue or fibrin) with various success. Preclinical data suggest that the haemostatic effect of collagen is stronger than that of oxidized cellulose, but no direct clinical comparison of their hemostatic performance has been published so far. This randomized, controlled, prospective trial evaluates the haemostatic effect of Lyostypt versus Surgicel in arterial bypass anastomosis. Twenty eight patients undergoing an elective peripheral vascular reconstruction due to peripheral vascular disease will be included. Suture hole bleeding occurring at the arterial bypass anastomosis using a PTFE prostheses will be stopped by the application of Lyostypt and/or Surgicel. The proximal anastomoses will be randomized intraoperatively. The patients will be allocated into four different treatment groups. Group1: Lyostypt distal/Surgicel proximal; Group 2: Lyostypt proximal/Surgicel distal; Group 3: Surgicel distal and proximal; Group 4: Lyostypt distal and proximal. Primary endpoint of the study is time to haemostasis. Secondary endpoints are the number of intraoperatively used haemostatic devices, postoperative mortality within 30 days as well as the intraoperative efficacy rating of the two devices evaluated by the surgeon. As a safety secondary parameter, the local and general complication occurring till 30 ± 10 days postoperatively will also be analysed. After hospital discharge the investigator will examine the enrolled patients again at 30 days after surgery.

Lahoti B et al in 2010 conducted a study on "Hemostasis achieved during topical application of feracrylum in hypospadias surgery" in which several beneficial effectiveness of the drug is found, it reduces the repetition of cauterization and surgical site tissue destruction, operative blood flow, surgical

wound edema, postoperative edema and complication. It posses antimicrobial property due to presence of synthetic polyacrylates and decreases postoperative infection. Its mode of action is via activation of thrombin, which continues to cause conversion of fibrinogen to fibrin and finally clot formation. Additionally, on coming in contact with serum proteins, a thin film is formed, finally a mechanical barrier is formed thus preventing exogenous contamination which is very beneficial. Feracrylum has a high molecular weight of 5,00,000 - 8,00,000 daltons, so no systemic absorption happens and no adverse effects on liver, kidney, adrenals, cardiovascular and hemopoietic systems is seen. It reduces capillary oozing and surface bleeding, and thus a clear field of surgery during surgery makes easy for surgeon to work. [7]

Bhagwat et al in 2001 did a study of comparing both Feracrylum and Povidone iodine. It was found that, Feracrylum is superior to povidone iodine for its antimicrobial properties. Povidone iodine is very good antimicrobial but Feracrylum is superior to povidone iodine suggesting it can be used frequently in minor surgical procedures. [8] The cost effect of the agent must also be noted. The new haemostatic agent like feracrylum is tried so that the surgeons expectations regarding controlling excessive loss of blood is fulfilled.

Malamquist et al in 2008 in his study evaluated the efficacy of the Hem con Dental dressing derived from the US military Hem con bandage combat wound dressing and whether early haemostasis affects Postoperative care and surgical healing outcomes following oral surgical procedures. All patients were required two or more surgical sites so they would have internal surgical. All patients taking oral

anticoagulants were included in the study. All HDD surgically treated sites including all patients taking DAT, achieved haemostasis in less than one minute the HDD has been proven to be a clinically effective haemostatic device that significantly shortens bleeding time including patients taking oral anticoagulants. Patients taking the HDD had surgical wound healing compared with control groups.

Motamedi K et al in 2012 conducted a split mouth study in thirty patients after tooth extraction. Patients were chosen randomly and they were without congenital bleeding disorders, systemic diseases, and not have taken any anticoagulant drugs. Dental cell is a local haemostatic, action depends on the building of haemoglobins to any cellulose, allowing the dressing to expand into a gelatinous mass, which acts both as scaffolding for clot formation and as a clot stabilizer. The cellulose tampon is a soft dressing that is made of cellulose fabric. It does not stick to the clot so it may easily be removed after haemostasis. In his study, after 2 minutes and 5 minutes post-extraction, the haemostatic tampon significantly reduced bleeding time. He denied the use of gauze after post-extraction where it should be in extraction socket for longer time period.

Soltani et al in 2014 studied on the effect of green tea extract on the bleeding control after extraction of posterior mandibular teeth concluded that decline in extraction bleeding socket as well as comparative reduction of oozing in normal patients in dental extraction cases. [11] In this study, where the effect of green tea extract on gingival bleeding after extraction of mandibular molars was investigated, most of the patients who were administered extract-free gauze (83.8%) had bleeding time more than 5 minutes, while only 22.6% of the patients

who used green tea extract-impregnated gauze experienced bleeding longer than five minutes. The effect of green tea on reduction of gingival bleeding and oozing, observed in this study, is probably due to its tannins which cause contraction of damaged tissues and capillaries with their astringent effect. This effect is another with their astringent effect is another possible mechanisms for haemostasis.

Evelyn GD et al in 2013 conducted a Dental treatment with 30% TCA showed that local treatment with 30% tricarboxylic acid added with trenaxamic acid 500gm which is coated with gauze and when placed on the hemorrhagic site, was able to stop the bleeding. [12] The use of tannic acid compounds is known among the best topical treatment for cessation of bleeding. The TCA at 30% has only haemostatic effect. When used in patients with conditions affecting the mucosa precautions should be short TCA application time and drying of the applicator to limit the mucosal contact. He observed a single case with local treatment of dichloroacetic acid combined with trenexamic acid placed on haemorrhagic site was able to stop the bleeding.

Kim S and Rethnam S in 1997 reported that a good haemostatic agent should stop bleeding in a minimal time, be easy to handle the device, should be biocompatible to living tissue, should not procrastinate or complicate healing, and should be relatively inexpensive and safe. All of the authors tried a haemostatic agent which is superior to one another in one aspect and also from economical aspect. Apparently no haemostasis agents meet all these conditions, because all of them produce adverse effects in varying degrees, thus posing a dilemma for clinicians when having to choose a haemostatic product. [13]

Singh J, et al in 2012 reported the clinical significance of hemorrhage depends on the volume and rate of bleeding. Rapid loss of up to 20% of the blood volume or slow losses of even larger amounts may have little impact in healthy adults. Bleeding that is confined within the body cavity and is not apparent on the surface is known as internal or concealed bleeding whereas, blood escaping through a wound in the skin is known as external bleeding. This article gives an overview on different types of hemorrhage, various local methods, different drugs used to manage bleeding during oral surgical procedure. Hemorrhage means the escape of blood from a blood vessel. Hemorrhage generally indicates extravasation of blood due to vessel rupture Blood carries oxygen and nutrients to the tissues and is vital for body functions, loss of blood due to any reason beyond a certain point is potentially life threatening and may lead to loss of life.

Selden HS in 1970 introduced bone wax to control bone crypt bleeding in periapical surgery, but bone healing is poor in the presence of material, connective tissue fibres appear and there is no bone or hematopoietic tissue presence. In addition it increases the susceptibility to infection, and causes chronic inflammation with foreign body reactions.

Lemon et al in 1993 conducted research and studied the effects of ferrisulphate in rabbit periapical tissues achieving hemostasis for 5 mins and normal healing with mild foreign body reaction – provided careful curettage of the cavity was performed and saline solution irrigation was used. Amine type sympathominetic vasoconstrictors such as epinephrine, noreepinephrine and phenylephrine have been used as topical agents for the control of bleeding in minor oral surgery cases.

Besner et al in 1972 suggested in his study suggested the use of this drug in minor oral surgery which produces a systemic cardiovascular response.

Littlejohn LF in 2011 reported uncontrolled hemorrhage remains one of the leading causes of trauma deaths and one of the most challenging problems facing emergency medical professionals. Several haemostatic agents have emerged as effective adjuncts in controlling extremity of hemorrhage. However, a review of the current literature indicates that none of these agents have proven superior under all conditions and in all wound types. This study compared several haemostatic agents in a lethal penetrating groin wound model where the bleeding site could not be visualized. A complex groin injury with a small penetrating wound, followed by transection of the femoral vessels and 45 seconds of uncontrolled hemorrhage, was created in 80 swine. The animals were then randomized to five treatment groups. Group 1 was Celox-A (CA), group 2 was combat gauze (CG), group 3 was Chitoflex (CF), group 4 was WoundStat (WS), and group 5 was standard gauze (SG) dressing. Each agent was applied with 5 minutes of manual pressure. Hetastarch (500 mL) was infused over 30 minutes. Hemodynamic parameters were recorded over180 minutes. Primary end points were attainment of rebleeding. No difference was found among the agents with respect to initial hemostasis, rebleeding, and survival.

Vickers FJ et al in 2001 evaluated haemostatic efficacy and the cardiovascular effects of ferric sulphate and of cotton balls impregnated with racemic epinephrine, both agents produces surgical hemostasis.

Vy et al in 2004 compared collagen sponges impregnated with 2.25% racemicepinephrine versus the same sponges impregnated with saline solution. No

differences between two groups in terms of either blood pressure or heart rate was found out. Good bleeding control was not achieved in three of 42 patients of the epinephrine group and in 5 to 6 subjects in the control group. They concluded that collagen sponges saturated with epinephrine afford excellent bleeding control and shows no evident changes in blood pressure or heart rate.

Von Arx et al in 2001 conducted two experimental studies that were carried out in rabbit skulls, testing a material which Von Arx has started to use in 2001 a paste containing aluminium chloride and Kaoline and which clinically proved to be effective. This product is known as expasyl and is usually used in gingival retraction.[21] In the other experimental study they compared the haemostasis efficacy and tissue reaction of bone wax, ferric sulfate, expasyl and a combination of expasyl and ferric sulfate was found to be most effective agent and the inflammatory tissue reactions were limited to the bone defects – never extending towards the surrounding tissues. The authors recommended to clean the bony cavity with a curette and freshening the bone with the round drill before closing the wound.[22]

Jensen et al 2010 in his study used the same study design, comparing the effects of 5 haemostatic protocols. Expasyl + stasis, expasyl + stasis + bone crypt freshening with a drill, spongostan, spongostan + epinephrine and electrocautery. The most effective methods for reducing bleeding were expasyl + stasis and electrocautery but these triggered adverse tissue reactions (necrotic bone, inflammatory cells and absence of bone repair.)

Aslam S et al in 2013 conducted a double blind study on the efficacy of local application of haemocoagulase solution in wound healing. A total of 20

patients who required dental extraction for orthodontic intervention were included. The haemocoagulase solution and placebo were locally applied to the extraction sockets and the efficacy of the solution in terms of bleeding control, anti-inflammatory responses, its antiseptic properties and the efficacy in wound healing were evaluated. The mean time requires to achieve hemostasis was found to be 1.37 minutes in side A and 2.33 minutes in side B (control). The sterile hemocoagulase solution produces a promoting action in wound healing. It has been studied and reported that this sterile haemocoagulase solution converts fibrinogen into fibrin and activates factor XIII. Factor XIIIa catalyses the cross linking of fibronectin and fibrin. Thus it can be inferred that the use of this sterile topical haemocoagulase solution following dental extraction enhances the normal healing process, by achieving faster haemostasis without any infection. The dental extractions were performed by the same operator using the same technique bilaterally, to avoid any deviation or discrepancy in the study.

Majumder K et al in 2014 did a prospective study on the efficacy agent after minor oral surgical procedures. The study is comprised of 150 surgical sites in 75 patients. The subjects were divided into 2 groups in which group 1 consists of 100 surgical sites in 50 patients. Group I comprised of simple extraction and group II comprised the group of patients with bilateral impactions. Haemocoagulase is applied topically on the extracted tooth socket and compared with extraction socket without haemocoagulase. In his conclusion he stated that the use of haemocoagulase after the minor oral surgery not only provides faster haemostasis but also enhances healing by rapid formation of healthy tissue and less chance of infection.

Borea G et al in 1993 reviewed a study on Tranexamic acid as a mouth wash in anticoagulant – treated patients undergoing oral surgery. An alternative method to discontinuing anticoagulant therapy. A double blinded randomized study was carried out to evaluate the clinical haemostatic effect of tranexamic acid mouthwash after dental extraction in 30 patients who received anticoagulant agents. Surgery was performed with a reduction in the level of anticoagulant therapy in the control group and with no change in the level of anticoagulant therapy in the group who received the tranexamic acid. He concluded that anticoagulant treatment does not need to be withdrawn before oral surgery provided that local antifibrinolytic therapy is instituted.

Tan SR and Tope WD in 2004 did a dermatologic surgery and compared the effectiveness of Microporous polysaccharide hemispheres for achieving haemostasis in Mohs Micrographic surgery. The microporous polysaccharide hemosphere did not have an increased incidence of active bleeding upon dressing removal.

Szpalski M et al in 2004 studied an overview of blood sparing techniques used in spine surgery during perioperative period. He stated that the decreasing bleeding is not only important for keeping the patient hemodynamic equilibrium but also for allowing a better view of the surgical field. The problems linked to blood loss and blood-sparing techniques in spine surgery have been less studied than in other fields of orthopedics, such as joint-replacement procedures. Decreasing bleeding is not only important for keeping the patient's hemodynamic equilibrium but also for allowing a better view of the surgical field. In spine surgery the latter

aspect is especially important because of the vicinity of major and highly fragile neurologic structures. The techniques and agents used for hemostasis and blood sparing in spinal procedures are mostly similar to those used elsewhere in surgery. Their use is modulated by the specific aspects of spinal approach and its relation to the contents of the spinal canal. Blood-sparing techniques can be divided into two categories based on their goals: either they are aimed at decreasing the bleeding itself, or they are aimed at decreasing the need for homologous transfusion. Various hemodynamic techniques, as well as systemic and local drugs and agents, can be used separately or in combination, and their use in the field of spine surgery is reported. The level of evidence for the efficacy of many of those methods in surgery as a whole is limited, and there is a lack of evidence for most of them in spine surgery. However, several blood-saving procedures and drugs, as well as promising new agents, appear to be efficient, although their efficacy has yet to be assessed by proper randomized controlled trials.

Lapierre F in 2008 on haemostatic agent in neurosurgery, neurosurgeons used fresh chicken breast as a topical hemostatic agent just before the beginning of the operation. At the same time, bone wax was used and is still use for bone hemostasis (Grant 2007). Bone wax was created by Sir Vickerhadenhorsely(1857-1916) from bees wax in 1892. Since this period different components were added to wax, but the common name remained as horsely wax. The first discussion for topical agents is due to Bergen who emphasized the role of fibrin in haemostasis. Gelatin haemostatic agents introduced in 1940 such as gelfoam and surgifoam. Cyanoacrylate adhesives developed by Dr. H.Coover in 1942. Microfibrillar collagen introduced in 1970. Oxified regenerated cellulose introduced in 1960.

Among the four devices, Tissucol, beriplast,the quixil, and tachosyl. Beriplast was the foremost fibrin sealant in consistently providing early hemostasis. Patches and pads are non-invasive hemostatic closure devices as described by Hirsch, Reddy and AI 2003 are mainly used to obtain hemostasis of percutaneous arteriotomy sites of arterial catheterization. It is mostly used in cardiac surgery and in interventional radiology.

Barners W in 1944 stated that the introduction by Infraham and Bailey of fibrin foam as a hemostatic agent in neurologic surgery marks a technical advance as significant as the earlier introduction of silver clip and the electrocautery. The control of hemorrhage from small or moderate sized vessels in the brain or spinal neuroaxis by electrocoagulation or clipping is relatively standardized and has been proved satisfactory. The control of capillary bleeding from the substance of the brain or spinal cord, from small vessels over the surface of the medulla or spinal cord or from the vascular supply of peripheral nerves cannot be accomplished by these destructive measures. Nor is it feasible to control gross hemorrhage from tumor beds or lacerated venous sinuses by these technics. For these purposes, cotton patties soaked in warm saline solution or muscle stamps have been used. As Ingraham has pointed out, everyday experience has indicated that these methods

Menovsky T et al in 2014, stated that new haemostatic powder (Gelitical ca powder) and its application in cranial neurosurgery. He report on the use of a new powder form of regenerated oxidized cellulose enriched with calcium (Geliticel ca powder) for haemostatic powder in intracranial surgery.

He stated that the main advantage of the powder form over regular oxidized cellulose is the no touch technique of application and leaves no excess haemostatic material behind which could possibly cause compression.

Schonauer C et al in 2004 reviewed the use of local haemostatics such as bone wax, gelatin, collagen and oxidized cellulose and states that each haemostatic agents should be used in specific type of spine surgery. Bipolar electric coagulation for controlling subcutaneous bleeding. Muscular dissection is performed by monopolar electric coagulation. Procedure of bone carries the risk of bleeding from cancellous bone which is controlled by bone wax. Epidural venous plexus increases the risk of fighting against low pressure, it is difficult to control and time consuming. During this step, oxidized regenerated cellulose and fibrillar collagen are very useful. The use of local agents to achieve hemostasis is an old and complex subject in surgery. Their use is almost mandatory in spinal surgery. The development of new materials in chemical hemostasis is a continuous process that may potentially lead the surgeon to confusion. Moreover, the more commonly used materials have not changed in about 50 years. Using chemical agents to tamponade a hemorrhage is not free of risks. Complications are around the corner and can be due either to mechanical compression or to phlogistic effects secondary to the material used. This paper reviews about twenty animal and clinical published studies with regard to the chemical properties, mechanisms of action, use and complications of local agents.

Satkurunath G and Royston D in 2008 reviewed hemostatic drugs in trauma and orthopaedic practice. They stated that rfVIIa is a newer drug that is

most often used as a salvage therapy in trauma and uncontrolled haemmorhage in major surgery when other measures have failed. Orthopaedic surgery and trauma that result in major blood loss increase morbidity and mortality. In trauma, uncontrolled hemorrhage is the leading cause of preventable death. In elective orthopaedic surgery, blood loss produces transfusion rates that vary from 11% to 65%, depending on the type of surgery. Blood transfusion may be a life-saving measure in hemorrhage but is an expensive resource that can result in a variety of problems for our patients. Allogenic transfusion carries the risk of infection transmission, immune suppression, anaphylaxis, volume overload, transfusion-related lung injury, and graft-versus-host disease. Transfusion of packed red cells can also cause hypothermia and coagulation factor deficiencies, which can lead to a coagulopathy, which may cause continued bleeding. Finally, transfusion may also be refused by patients because of religious or personal beliefs, even in emergency situations.

Aubourg et al in 2011 did a study on surgical hemostatic agents; assessments of drugs and medical devices. A metaanalysis and 52 controlled randomized studies were selected involving cardiac or vascular surgery, ENT surgery, gastrointestinal surgery, urology and orthopaedic surgery. Groups could not find clear difference in various specialities. To evaluate the clinical value of these products , methodologically sound clinical studies are necessary. Surgical hemostatic agents are indicated to improve hemostasis when conventional techniques (compression, sutures or electrocoagulation) are inadequate. This evaluation included one class of products containing some form of human fibrinogen and thrombin and eight classes of medical devices and automated devices to prepare autologous fibrin. The assessment was based on a systematic review of

the literature and expert opinion of health care professionals. The main measures of effectiveness of hemostatic agents were the success rate as expressed in terms of the time necessary to obtain adequate hemostasis, the volume of intra and/or postoperative blood loss, the need for blood transfusions, complication rate, duration of operations and hospital stay. A meta-analysis evaluated blood derived agents (fibrin sealants) while the other half evaluated medical devices. Surgical hemostatic agents can be used in ad hoc settings, as a complement to conventional methods to control persistent bleeding after conventional hemostatic techniques, or when abundant bleeding has led to biologic hemostatic disorders.

Saha SP et al in 2011, on use of a fibrin sealant as a hemostatic agent in expanded poly tetrafluoroethylene graft placement surgery. A three treatment groups were analysed and it was found that fibrin sealant has a strong safety profile and suggests that it is an efficacious hemostatic agent in eptfe graft placement surgery. The low thrombogenicity, porosity, and limited elasticity of expanded polytetrafluoroethylene (ePTFE) vascular grafts, although beneficial, may exacerbate the problem of suture-line bleeding at vascular anastomoses and consequently lead to increased operating times. The overall objective of this prospective, randomized, controlled, subject-blinded, multicenter phase 2 study was to evaluate the efficacy and safety of a fibrin sealant containing 500 IU/mL thrombin and synthetic aprotinin for hemostasis in subjects undergoing vascular surgery and receiving prosthetic ePTFE vascular grafts.

Boylan JF et al in 1996 conducted a study on trenexamic acid on blood loss, transfusion requirements and coagulation factor used in primary

orthoptic liver transplantation. He further stated that trenexamic acid significantly reduces intraoperative blood loss and peri-operative donor exposure in patients with end stage parenchymal liver disease who are undergoing orthoptic liver transplantations, with marked reduction in platelet and cryoprecipitate requirements.

Karagiannis et al in 2006 conducted a study on experience from the use of absorbable type 1 collagen as hemostatic agent in obstetric and gynaecological operations. In those all cases of post partum hemorrhage due to atonic uterus, they have packed the uteriene cavity with tampon covered by hemostatic type1 collagen . Type 1 collagen is a material of 96% purity and ph - 5.5 to 6.5/ .type1 collagen is very effective in controlling hemorrhages due to atonic uterus and in cases of caessarian section due to low lying placenta and placental praevia. It can be used where there is significant blood loss and where there is imminent disseminated intravascular coagulation. During the third stage of labour there are a lot of causes of significant hemorrhage. The commonest causes of acute hemorrhage are the uterine atony, the retained placenta, the lower tract lacerations, uterine rupture, placenta accreta, hereditary coagulopathy. Also, there could be significant bleeding, during caesarian section, usually at the time of removal of the placenta in cases of low lying placenta or placenta previa. In order to deal with these problems successfully, general and specific measures are being taken. In cases of atonic uterus when all the other methods were unsuccessful we have to proceed to ligation of the internal iliac artery or even hysterectomy. By placing the collagen type I over the bleeding surfaces we have realized that in a very short period of time, there has been satisfactory control

of the bleeding and immediate clinical improvement of the patient. In four out of five obstetrical cases that we have used the type I collagen, we have managed to avoid the hysterectomy.

Casilla E et al in 2013 studied on the use of haemostatic agents (tachosil and tabotamp) in the surgical conservative treatment of uterine myomas, and their operative outcomes, 59 premenopausal women were included in the study, 25 were given hemostatic agent and another 25 used as a control group. He concluded that the application of hemostatic agent reduces the postoperative adhesion after laparotomic myomectomy so as to guarantee a better presentation of fertility.

Leon A et al in 2014 did a study on dental management of patients receiving anticoagulant and/or antiplatelet treatment. They identified adequate hemostasis necessary for dental treatment, since bleeding give rise to complications. The patients tend to an increased risk of bleeding due to the use of anticoagulant drugs is a challenge in the daily practice of dental surgeon. Adequate knowledge of the mechanisms underlying hemostasis, and management of such patients, are very important issues. A study is made of the anticoagulant drugs currently available on the market, with evaluation of the risks and benefits of suspending such drugs before dental extraction. A review is made of the current protocols used in these patients with complementary hemostatic tests to minimize any risks derived from dental treatment. Doctors consider that patient medication indicated for the treatment of background disease should not be altered or suspended unless so indicated by the physician. Local hemostatic measures is enough for bleeding problems resulting from dental extraction.

Verma G in 2014 in his study on dental extraction concluded that extraction can be performed safely in patients on aspirin therapy. Cardiology patients taking aspirin drug require extractions for their diseased teeth. It is a common among treating surgeons to stop aspirin before to tooth extraction because of bleeding. This practice is a causative factors for the patient to thromboembolic events. This practice is based on isolated case reports of excessive bleeding with aspirin therapy. The latest recommendations are in favor of continuing aspirin therapy during simple tooth extraction as the bleeding complication incidence is minor one and can be controlled with local hemostasis measures.

Perry DJ et al in 2007 done a study on guidelines for the management of patients on oral anticoagulants requiring dental surgery. The objective of these guidelines is to provide healthcare professionals, including primary care dental practitioners, with clear guidance on the management of patients on oral anticoagulants requiring dental surgery. The guidance may not be appropriate in all cases and individual patient circumstances may dictate an alternative approach. The writing group produced the draft guidelines, which were subsequently revised by consensus by members of the Haemostasis and Thrombosis Task Force of the British Committee for Standards in Haematology. The guidelines were then reviewed by a sounding board of approximately 100 UK haematologists, the BCSH (British Committee for Standards in Haematology), the British Society for Haematology Committee, the British Dental Association (BDA), and the National Patient Safety Agency (NPSA) and comments incorporated where appropriate. Criteria used to quote levels and grades of evidence are as outlined in appendix 3 of the Procedure for Guidelines Commissioned by the BCSH.

Pototski M and Amenábar J in 2007 studied on the dental management of patients receiving anticoagulation or antiplatelet treatment. Antiplatelet and anticoagulant agents have been thoroughly researched and developed as therapies in the prevention and management of venous and arterial thrombosis. Antiplatelet and anticoagulant drugs have also been associated with an increase in the bleeding time and risk of postoperative hemorrhage. Some dentists recommend the patient to stop the therapy for at least 3 days before any oral surgical procedure. Stopping the use of these drugs exposes the patient to vascular problems, with the potential for complication. This article reviews antiplatelet and anticoagulant drugs in use today and explains the dental management of patients on these drugs, when subjected to minor oral surgery procedures. On conclusion that the optimal INR value for dental surgical procedures is 2.5 because it minimizes the risk of either hemorrhage or thromboembolism. Minor oral surgical procedures, tooth extraction and periodontal surgery, can safely be done with an INR lower than 4.0.

Sidana S and Galinde J in 2011 reviewed study on the contemporary management of patients on warfarin, aspirin and clopidogrel requiring dentoalveolar surgery. Patients with a variety of medical conditions often receive aspirin, warfarin or clopidogrel to prevent complications from atrial fibrillation, thromboembolisms or stroke. Although these medications can be lifesaving; it also can put patients at greater risk of experiencing haemorrhage after dental surgery. Therefore, a decision must be made whether to interrupt or continue anticoagulant treatment in patients undergoing various dental procedures. Having presented a review of this topic, including a brief description of the more commonly encountered anticoagulant and antiplatelet medications and the current recommendations for the surgical management of these patients.

Bajkin BV et al in 2014 studied on dental extractions and risk of bleeding in patients taking single and dual antiplatelet treatment. The aim was to evaluate the effects of single and dual antiplatelet treatment on postoperative bleeding in patients having dental extractions. The prospective clinical study included 160 patients who were taking antiplatelet drugs. The first group were taking 2 drugs, mostly aspirin and clopidogrel, and the second group were taking a single antiplatelet drug in the form of aspirin , clopidogrel , and ticlopidine . All patients had simple dental extractions, and local haemostasis was with resorbable collagen sponges, without suturing of the wound. The control group comprised 105 healthy subjects with a similar number of dental extractions. Bleeding was an "event" if it continued for more than 12 h, made the patient call or return to the dental practice or emergency department, induced a large haematoma or ecchymosis within the oral soft tissues, or required blood transfusion. A total of 110 teeth were extracted on 59 occasions in the dual drug group, and 232 teeth on 128 occasions in the single drug group. Bleeding was recorded after extraction in only one patient on dual aspirin–clopidogrel treatment, which was mild and easily controlled by local haemostasis. The incidence of postoperative bleeding did not differ significantly among the three groups. However, the wound was sutured to achieve effective initial local haemostasis in occasions of tooth extractions in the dual and single drug groups, and none in the control group. Patients taking single or dual antiplatelet drugs may have teeth extracted safely without interruption of treatment using only local haemostatic measures.

AlHarkan AM and AlAyoub GA. in 2012 studied on the possible outcome of antiplatelet and anticoagulant medications be discontinued before minor oral surgery procedures. Thromboembolic events are among the major causes of mortality and

morbidity. To decrease the incidence of such events, physicians prescribe one or more antithrombotic medications for patients at risk. These medications include antiplatelet agents, fibrinolytic drugs and anticoagulants. Patients taking antithrombotic agents occasionally require minor oral surgery. Antiplatelet drugs, which decrease the aggregation of platelets and prevent thrombus formation, are used to treat or prevent thrombotic cardiovascular or cerebrovascular diseases. The most common antiplatelet medications are the cyclooxygenase inhibitors (e.g., ASA) and the adenosine diphosphate (ADP) receptor inhibitors (e.g., clopidogrel). Although antiplatelet drugs can double bleeding time, this time may remain within or just above the normal limit and, thus, have no clinical significance. ASA achieves its antiplatelet effect by inhibiting cyclooxygenase 1 (COX-1), preventing the formation of prostaglandin H2 and thromboxane A2. Thromboxanes are responsible for platelet aggregation. Although some dental clinicians ask their patients to stop ASA days before a minor oral surgery procedure to prevent potential bleeding, studies have shown that stopping low-dose ASA (75–100 mg) is unnecessary. In most cases, postoperative bleeding experienced by patients taking ASA does not differ from that in patients not taking ASA. In addition, one study has shown that there is no need to stop higher doses of ASA (325 mg) when performing single tooth extractions.Therefore, stopping low-dose ASA (and in certain cases higher doses) as a routine practice before minor oral surgery procedures should be abandoned. In fact, stopping ASA may create a higher risk of an adverse event (e.g., acute coronary event) than the potential risk of intra- or postoperative bleeding.

O'Connell JE and Leo FA in 2014 on their study on new oral anticoagulants and their implications for dental patients. Anticoagulation therapy is used in several conditions to prevent or treat thromboembolism. Over the last 40

years, warfarin has been the oral anticoagulant of choice and has been considered the mainstay of treatment. However, its use is limited by a narrow therapeutic index and complex pharmacodynamics, necessitating regular monitoring and dose adjustments. Recently, two new oral anticoagulants - dabigatran etexilate (a direct thrombin inhibitor) and rivaroxiban (a factor Xa inhibitor) - have been approved for use in North America and Europe. Unlike warfarin, dabigatran and rivaroxiban are relatively small molecules that work as anticoagulants by targeting specific single steps of the coagulation cascade. Their advantages, relative to warfarin, include: predictable pharmacokinetics; limited food and drug interactions; rapid onset of action; and, short half-life. They require no monitoring. However, they lack a specific reversal agent. The number of patients taking dabigatran and rivaroxaban is increasing. Therefore, it is inevitable that dentists will be required to perform invasive procedures on this cohort of patients. This paper outlines the various properties of the new oral anticoagulants and the most recent guidelines regarding the management of these dental patients taking these medications.

Little JW et al in 2002 studied Antithrombotic agents: Implications in dentistry. Thrombosis and the complicating emboli that can result are important causes of illness and death. Thrombosis is of greater overall clinical importance in terms of morbidity and mortality than all of the hemorrhagic disorders combined. Agents such as heparin, low–molecular weight heparin, warfarin, aspirin, ticlopidine, clopidogrel, and tirofiban are used to prevent venous or arterial thrombosis. Patients taking these antithrombotic agents may be at risk for excessive bleeding after invasive dental procedures. The current antithrombotic agents used in medicine are reviewed, and the dental management of patients taking these agents is discussed.

Castelvecchi AN and Crump LN in 2002 reviewed the study on Oral Anticoagulants and Dental Procedures. Anticoagulants and antiplatelets are commonly used for various conditions including the treatment and prevention of cardiac disease, cerebral vascular accident, and thromboembolism, in both the inpatient and outpatient settings. As such, dental professionals will encounter many patients taking these medications. For these patients, several factors should be considered prior to a dental procedure; the indication for anticoagulant or antiplatelet therapy, bleeding risk, and thromboembolic risk must be assessed prior to interruption of therapy. Evaluating the risk versus benefit of continuing therapy can assist in determining if and when it is appropriate to interrupt therapy. Additionally, patients receiving anticoagulant and antiplatelet medications are frequently managed by different healthcare providers and specialists, so it is important to inform other providers if alteration of therapy is warranted, and provide clear instructions and education to both the patient and caregivers. The management of these agents prior to dental procedures can be complex due to the potential to prolong bleeding times, however recent studies and guidelines suggest that these medications can be safely continued for most minor dental procedures.

Materials & Methods

Study design:

This is an comparative interventional study for evaluating and comparing the post-extraction bleeding stoppage by using hemostatic agent coated gauze versus standard gauze in dental extraction.

Study setting:

All patient who seems to fit the Inclusion and exclusion criteria would be recruited.

The patient is recruited to the minor OT, Department of Maxillofacial surgery, Sree Mookambika Institute of Dental Sciences, Kulasekharam.

Approximate total duration of the study:

One month

Number of groups to be divided:-

Two groups

Description of the groups:-

Ten subjects reporting for therapeutic dental extraction is taken in to consideration. One group is study group and the another is control group. Extraction is carried out either in the right and left quadrant of the same jaw or between upper and lower jaw. Whatever may be the teeth extracted, both groups are present in same patient only.

Group I – Feracrylum coated gauze is placed in extraction socket

Group II – Standard gauze is placed in extraction socket

Sample size of each group

10 patients

Total sample size of the study

10 patients

Scientific basis of sample size used in study

Sample size is calculated from $n = \frac{2pq(z\alpha Xz\beta)^2}{(p1-p2)^2}$

Where $P = \frac{P_1+P_2}{2}$

q =1-P

P_1 = proportion of 1 group.

P_2 = proportion of 2 group.

Zα = 1.96

zβ = 0.84.

From the study (10)

$n = \frac{2X100X48(1.96X0.84)^2}{(100-48)^2}$

n = 10.842532

So sample size is 10 cases

Sampling technique need:

A systemic random sampling technique is used.

SELECTION CRITERIA:

Inclusion criteria

Patient were selected from those who were referred for extraction of one of their mandibular molars and premolars from the department of orthodontics.

- Healthy male and female.
- Age between 18 - 55 years.

- Patient indicated for therapeutic extraction on same side and contralateral side of the same quadrant or between extraction of teeth in upper and lower jaw.

Exclusion criteria

- Known case of blood disorders.
- History of intake of asprin or other drugs that interfere with coagulation in the last one month.
- no acute or uncontrolled infection or inflammation at the surgery site.
- Patient having large periapical lesion requiring open surgery were excluded.
- No malignancy at the surgical site.
- No history of exposure of radiation at the extraction site.
- Not using corticosteroid and contraceptive drug for the past one month.
- Participant should not have smoking habit.
- Must not have hypertension, diabetes, thyroid disorder.

Placebo used:

- No placebo was used in this study

Drug used:

- Feracrylum Gel

Drugs/Medical devices used:

- Drugs / medical devices used in for newer indication

  Feracrylum is commonly used as a haemostatic agent.

- Drugs / medical devices used in for first time in human beings.

  It is already used in human beings

- If used for newer Indication / first time in human beings, whether the permission obtained from the drug controller general of India (DCGI)

  Feracrylum drug is approved by CDSCO

- Formulation of the drug used

  Gel.

- Name of the drug / medical device used

  (Non proprietary name, Brand Name, company (Manufactures details) – Feracrylum / hemolok/ Themis Medicare)

- Dose of the drug used:

  Gel – Applied as a thin film as 1ml of gel in gauze.

- Frequency of the drug used:

  Only one time in fresh bleeding site.

  Can be used for another time if bleeding is not stopped.

- Route of the drug used:

  Applied topically.

- Duration of the drug used:

  Can be used till bleeding is stopped within physiological range

- Steps to be taken to prevent Adverse drug reaction

  Protocol instructed by Central drug standard control organisation (CDSCO) is followed.

- In case of severe Adverse drug reaction, mode of Management

  Emergency treatment available at Sree Mookambika Institute of Medical science nearby Department of Maxillofacial unit. Sree Mookambika institute of dental science.

- In case of drug related injury, agreement of compensation

  Agreement endorsed.

- Any other relevant details:

  Not applicable.

Parameters in this study:

- Duration of active bleeding (at two and five minutes after extraction)
- Continued bleeding.
- Cessation of the bleeding.

Methods/ technique/ instruments/reagents /kit:

- Patients whose teeth indicated for extraction by forceps were chosen.
- Adequate diagnostic procedures like iopa are taken.

Pre- operative assessment:

- Regarding absence or presence of lamina dura, Tooth position and amount of bone coverage of tooth are diagnosed.
- By removal of teeth which includes injection of local anesthesia, elevation of flap, extraction of teeth by forceps and suturing the wound.
- Standard Gauze and gauze coated with Hemostatic agent are required.

Procedure in Detail.

Ten patients reported for extraction on both sides of jaws are considered. Patients requiring atleast two symmetrical teeth in both sides of the upper and lower jaw were chosen or any teeth between upper jaw and lower jaw is considered.

By selection of case for extraction of teeth eg. Molars, pre molars, the area were the teeth to be extracted was anesthetized using the solution of lidocaine 2%/epinephrine1/80000.

The procedure was done as a simple forceps atraumatic extraction without bone removal and odontectomy with or without flap removal(in case of therapeutic extraction of premolars) in all quadrant. Both the teeth in same side and contralateral side were extracted by one practitioner only. The extraction on one side is carried out in one day and other side on another day or both sides simultaneously on one day itself.

In study group:

The formulation of drug is used in gel form and 1 ml of gel is taken and applied as a thin coating in gauze. Gauze piece coated with haemostatic agent is placed in extraction socket. Mechanical pressure was applied by instructing the patient to bite down on the gauze for two minutes. All of the extraction sites was evaluated for bleeding at two and five minutes after extractions and then the dressings were removed. As in some patients bleeding persisted, so gauze was retained until the bleeding is stopped and the wound is sutured. If suturing is not done for some cases the patient is sent home as soon as possible after confirmation of arrest of bleeding.

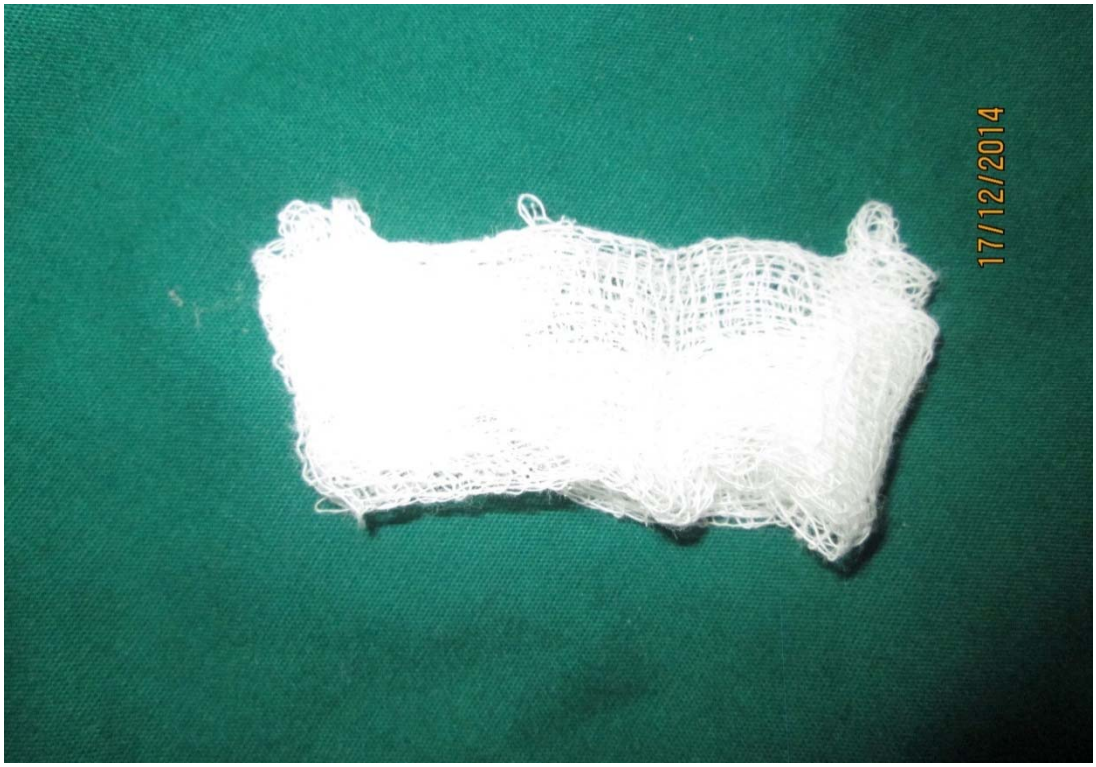
The duration of the active bleeding, continued bleeding, cessation of the bleeding were analysed. All the analysis was done by stop watch device and by surgeons observations (whether the bleeding is continued or stopped).

In control group:

The standard gauze piece is placed in extraction site by asking the patient to bite down for two minute. All of the extractions sites was evaluated for two and five minutes and the duration of bleeding, continued bleeding and the stoppage of bleeding is analysed by stopwatch and by surgeons observation.

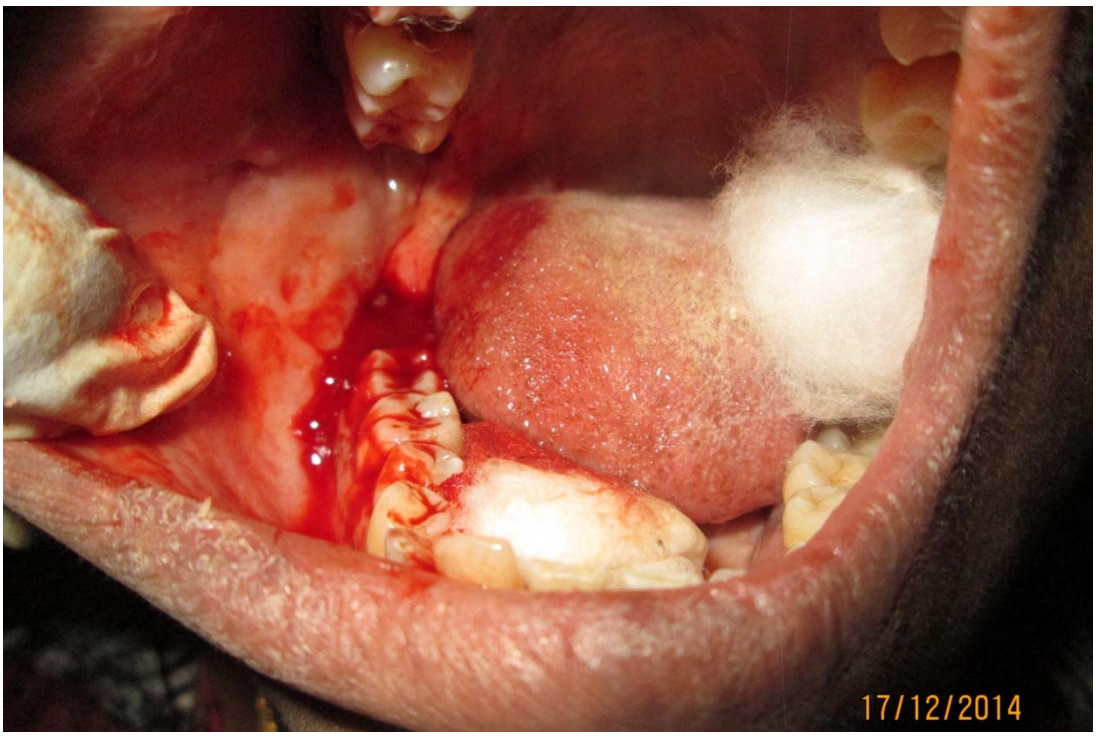
ARMAMENTARIUM

FERACRYLUM GEL



GAUZE

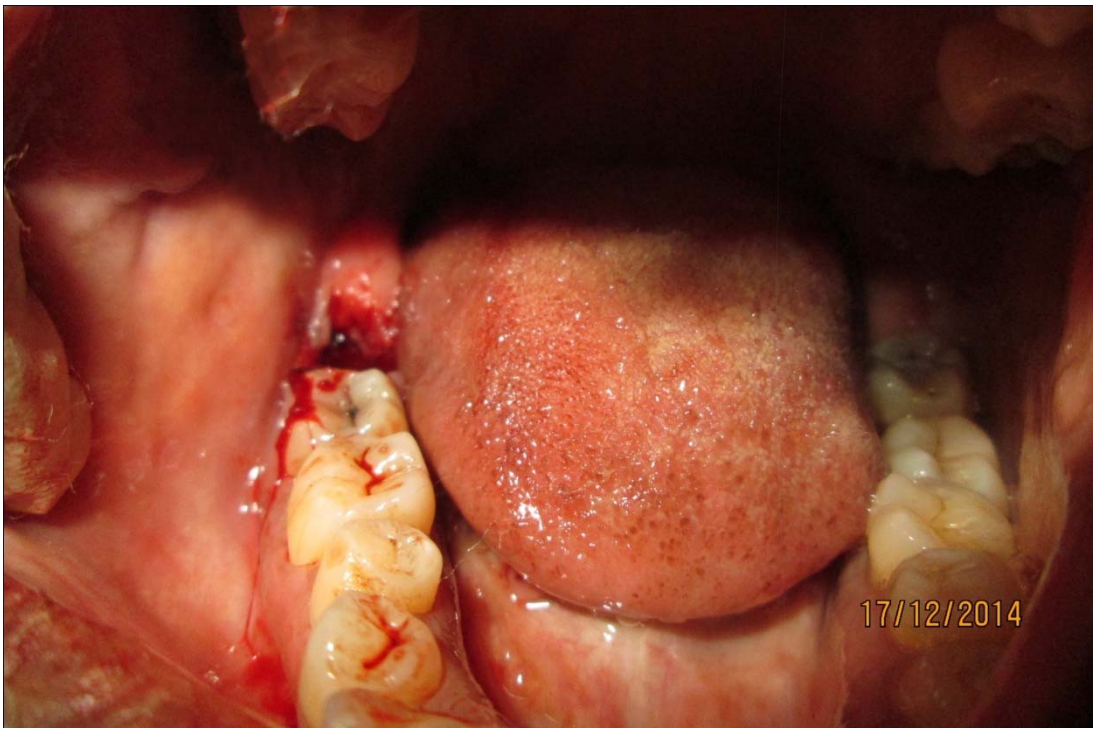
SIMPLE FORCEPS EXTRACTION



BLEEDING IMMEDIATELY AFTER EXTRACTION

FERACRYLUM GEL COATED ON GAUZE

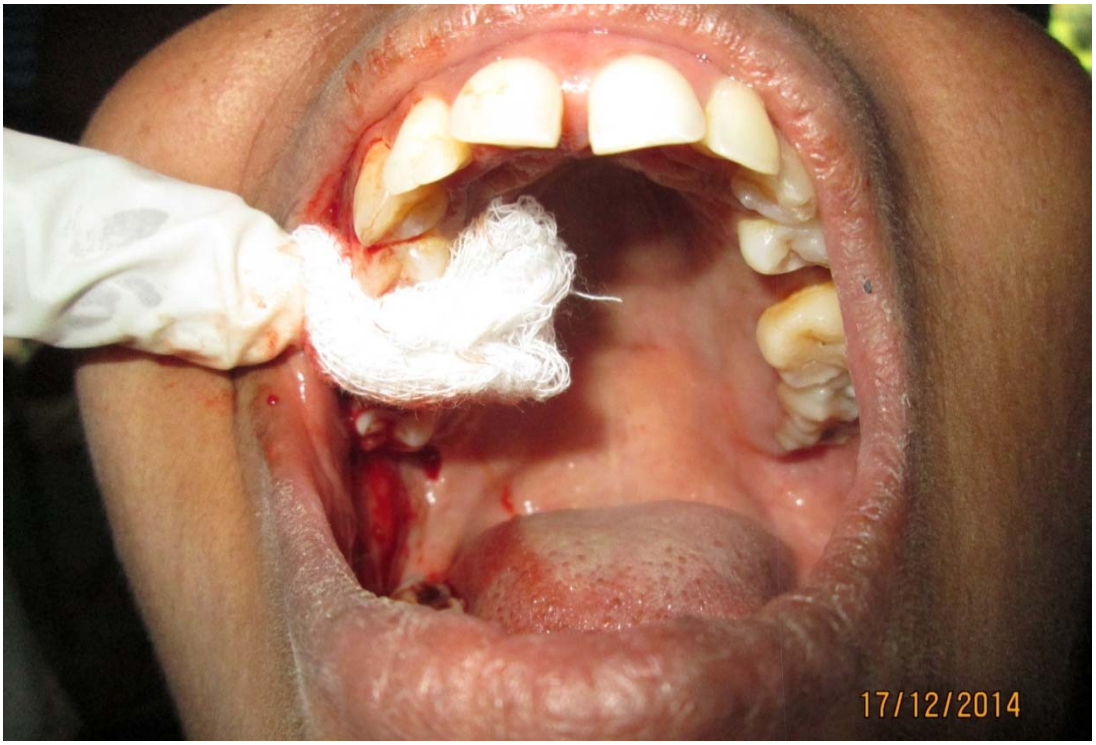
FERACRYLUM GEL COATED GAUZE IS PLACED OVER THE EXTRACTION SOCKET



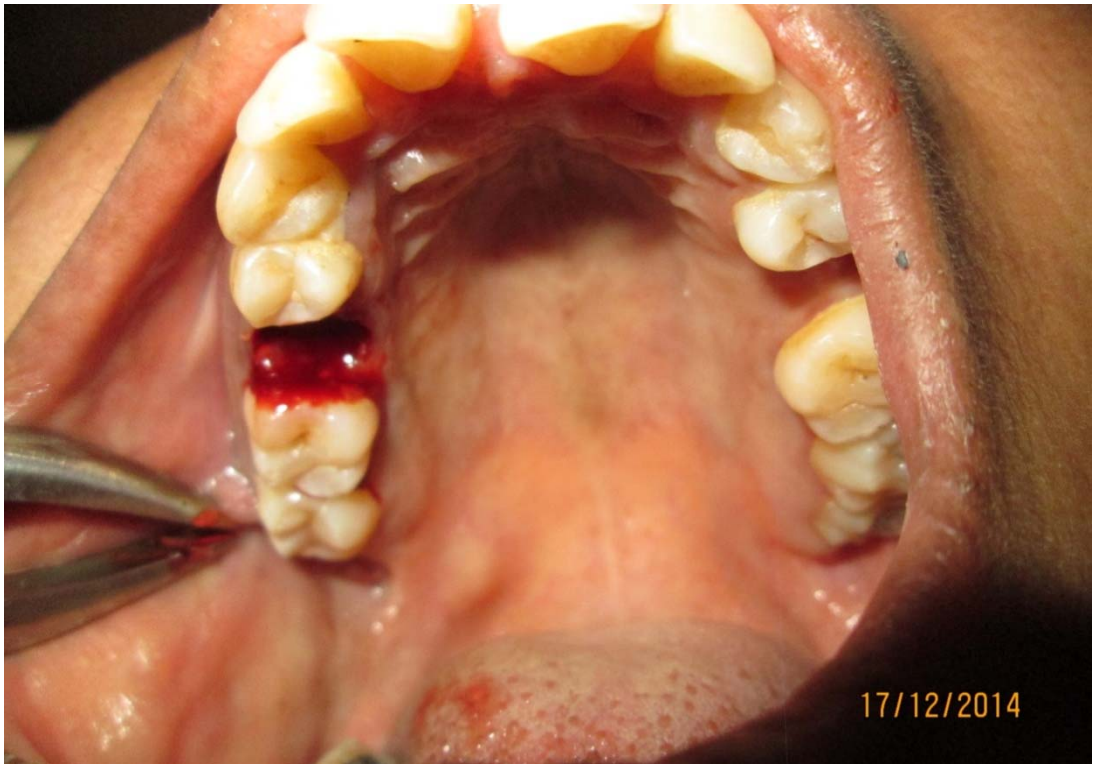
AT TWO MINUTES

AT TWO MINUTES AND THIRTY SECONDS

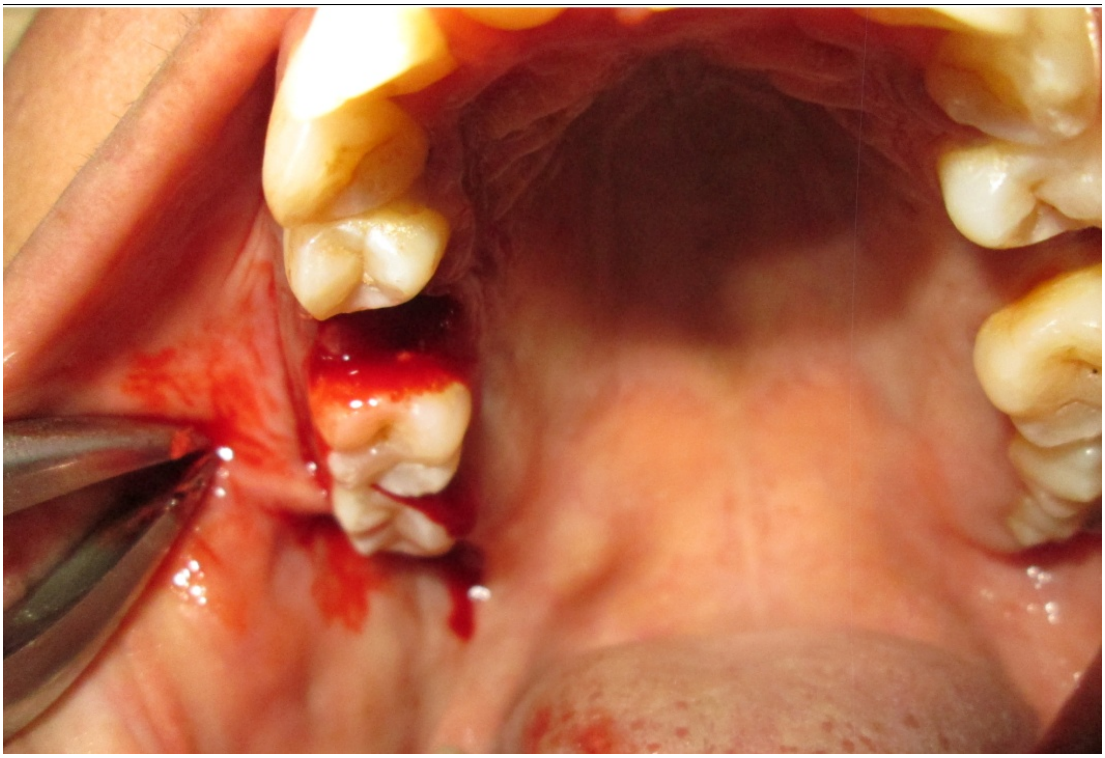
SIMPLE FORCEPS EXTRACTION



GAUZE IS PLACED OVER THE EXTRACTION SOCKET

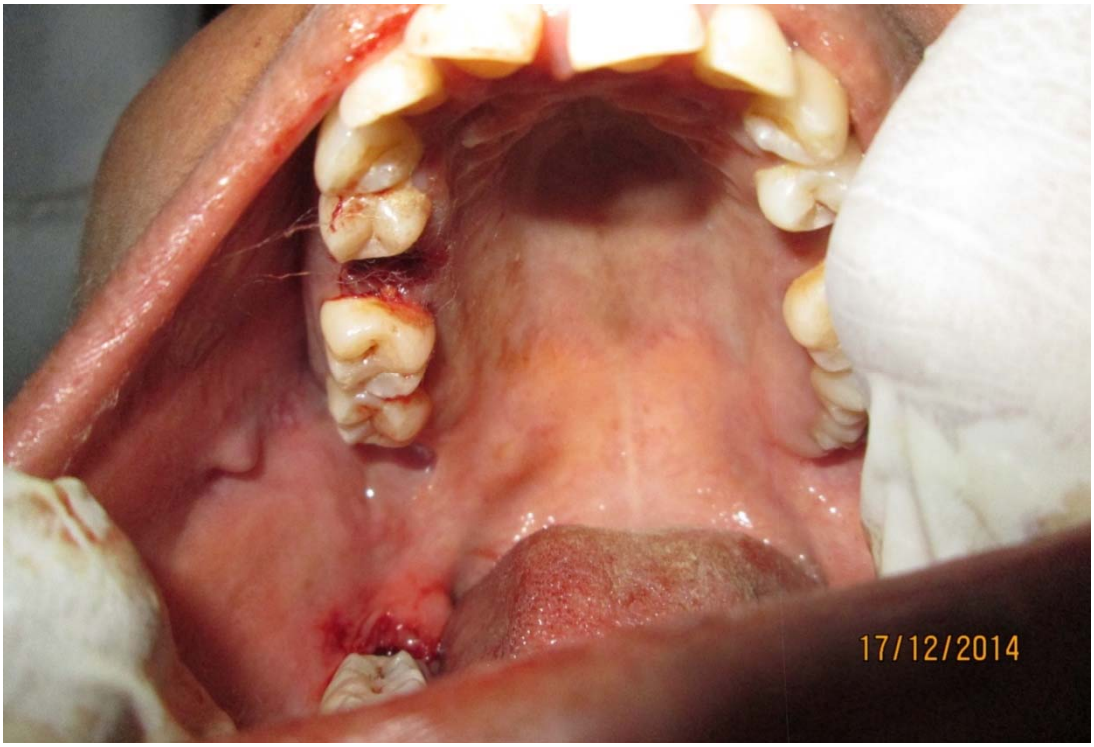


AT TWO MINUTES



AT FIVE MINUTES

FINALLY PLACEMENT OF ONLY GAUZE AFTER FIVE MINUTES



AFTER 10 MINUTES

Results

Statistical analysis

The data analyzed by SPSS (16.0) version. Unpaired t test and Chi Square test applied to find statistical significant between the groups. P value less than 0.05 ($P<0.05$) considered statically significant at 95% confidence interval.

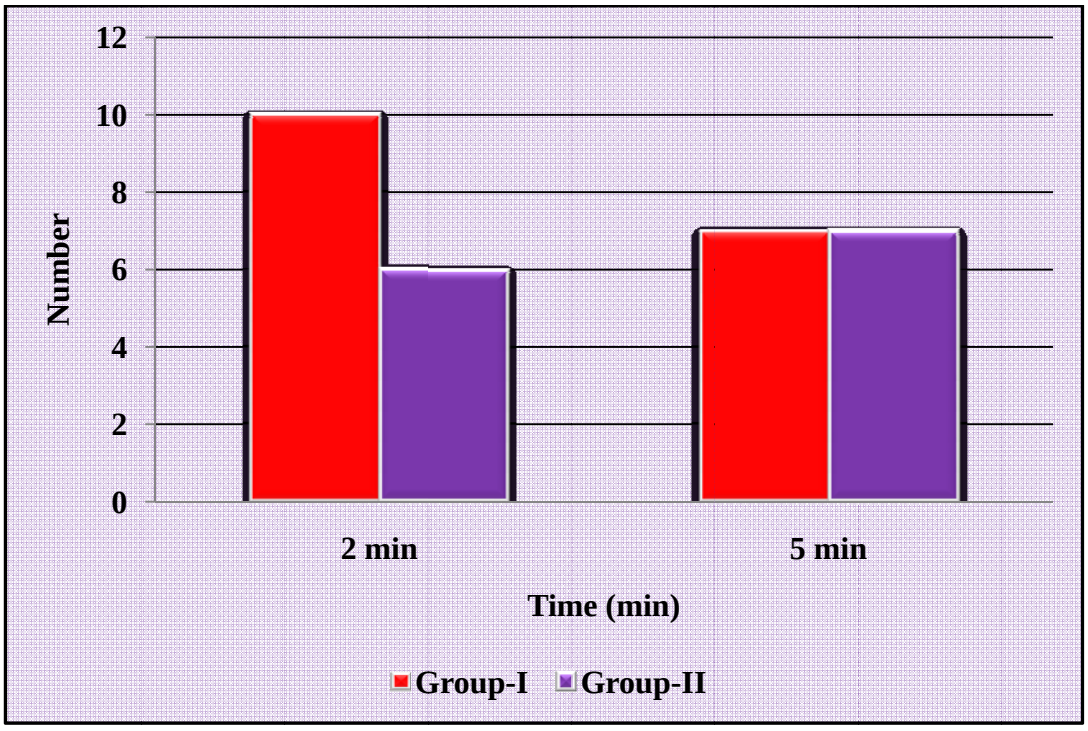
Table-1: Comparison of continuous bleeding values between the groups

Groups	2 min		5 min	
	Number	**Percentage (%)**	**Number**	**Percentage (%)**
Group-I	10	100	7	70.00
Group-II	6	60.00	7	70.00

Group I – Only gauze is placed in extraction socket

Group II – Feracrylum coated gauze is placed in extraction socket

Graph-1: Comparison of continuous bleeding values between the groups



Group I – Only gauze is placed in extraction socket

Group II – Feracrylum coated gauze is placed in extraction socket

In comparison of continuous bleeding at 2 minutes feracrylum is not statistically significant with the standard gauze

Table-2: Comparison of mean cessation of bleeding values between the groups

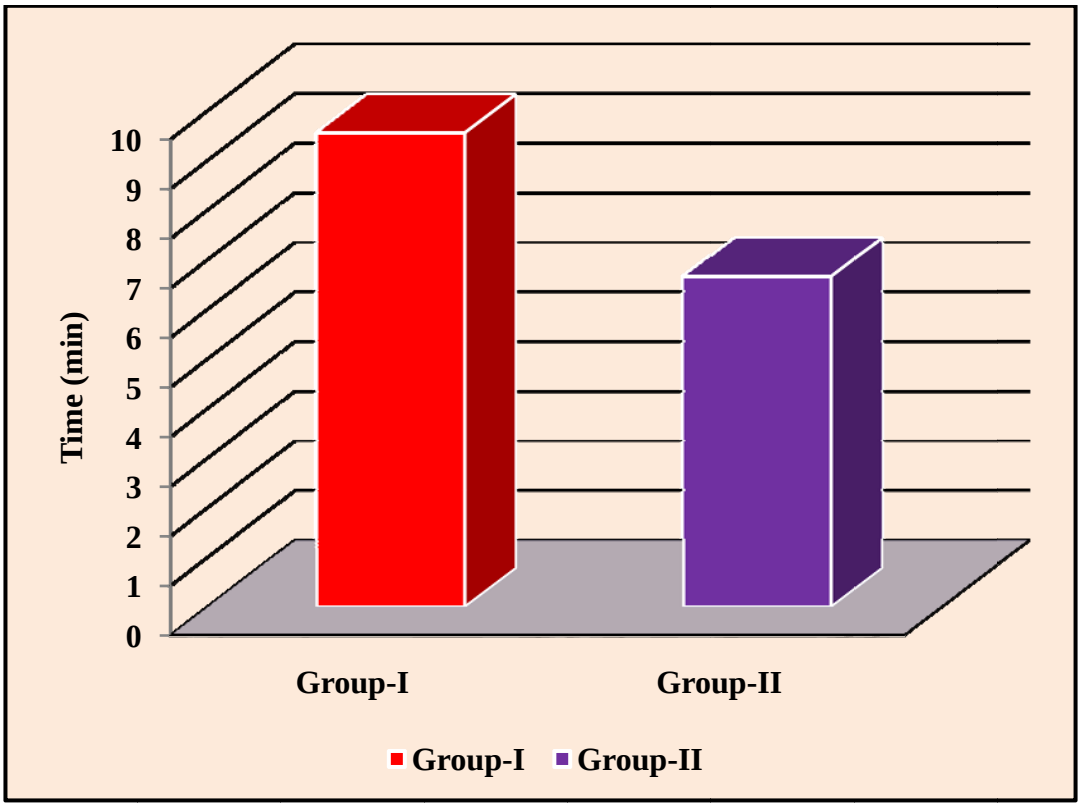
Groups	Cessation of bleeding (min) (MEAN±SD)	P value
Group-I	9.54±1.89	**0.001**
Group-II	6.65±0.96	

(*P<0.05 significant compared group-I with group-II)

Group I – Only gauze is placed in extraction socket

Group II – Feracrylum coated gauze is placed in extraction socket

Graph-2: Comparison of mean cessation of bleeding values between the groups



Group I – Only gauze is placed in extraction socket

Group II – Feracrylum coated gauze is placed in extraction socket

In comparison of cessation of bleeding, feracrylum is statistically significant with the standard gauze

Table-3: Comparison of mean bleeding time values between the groups at 2 min

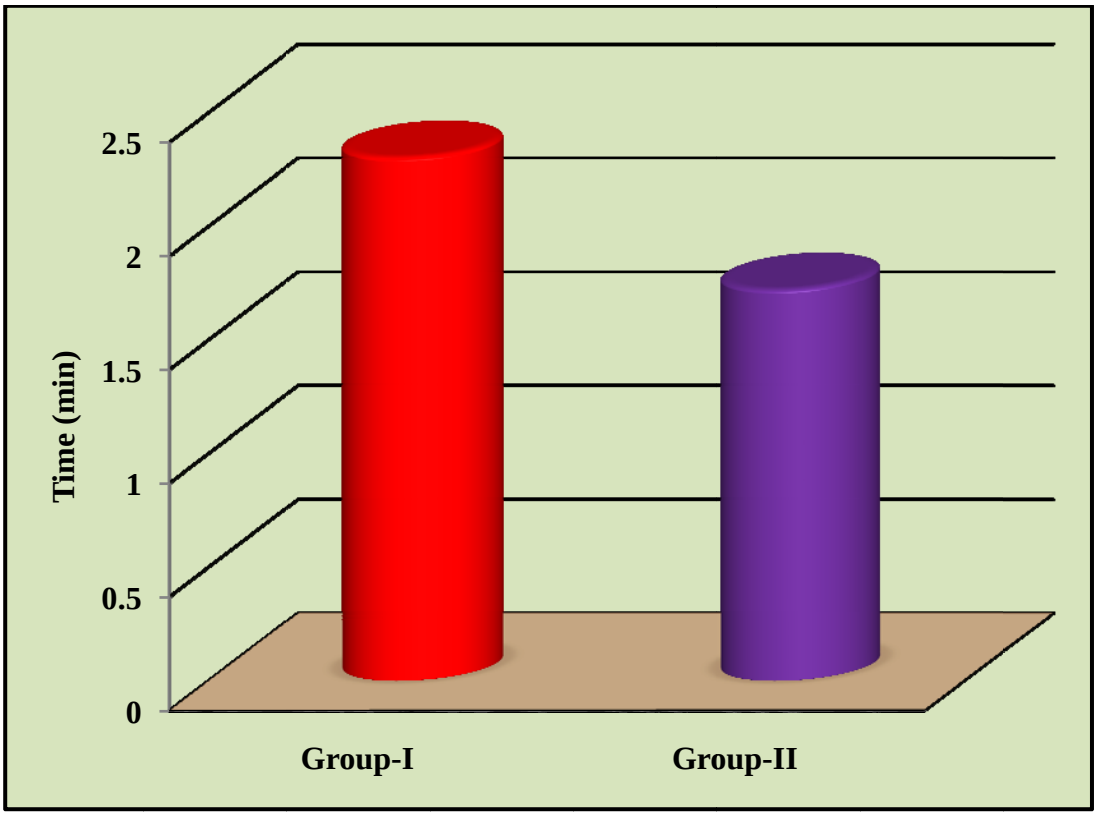
Groups	Bleeding time (min) (MEAN±SD)	P value
Group-I	2.30±0.01	**0.001**
Group-II	1.72±0.46*	

(*P<0.05 significant compared group-I with group-II)

Group I – Only gauze is placed in extraction socket

Group II – Feracrylum coated gauze is placed in extraction socket

Graph-3: Comparison of mean bleeding time values between the groups at 2 min



Group I – Only gauze is placed in extraction socket

Group II – Feracrylum coated gauze is placed in extraction socket

In comparison of mean bleeding time at 2 minutes feracrylum is statistically significant with the standard gauze

Table-4: Comparison of mean bleeding time values between the groups at 5 min

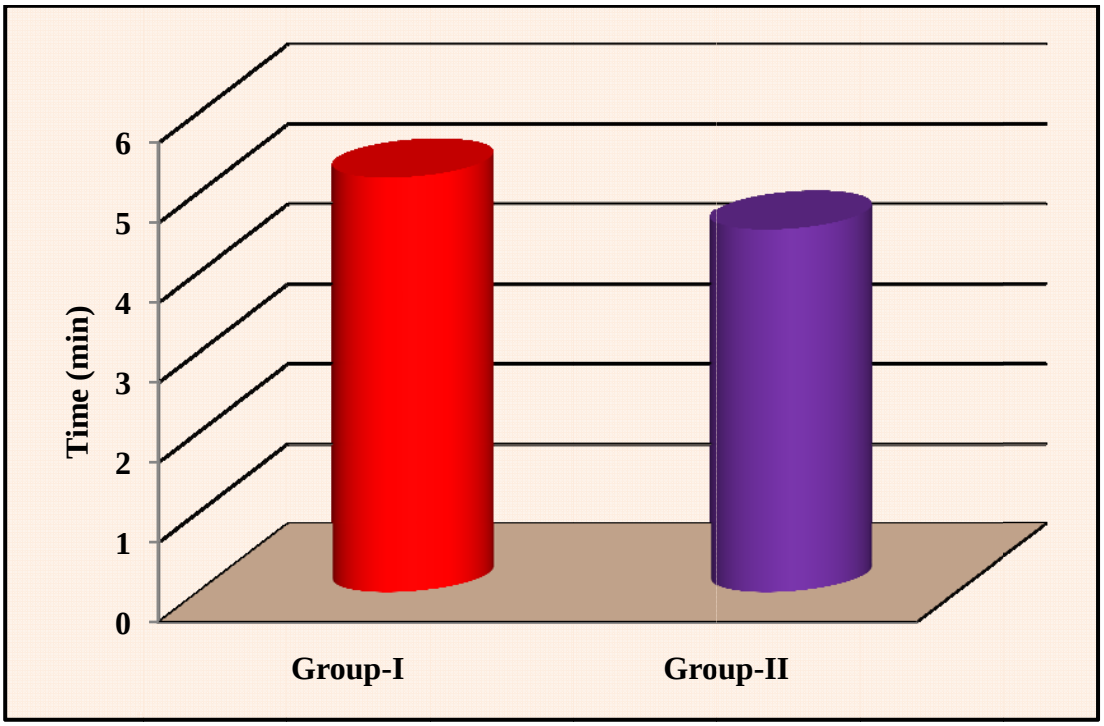
Groups	Bleeding time (min) (MEAN±SD)	P value
Group-I	5.18±0.38	**0.005**
Group-II	4.53±0.52*	

(*P<0.05 significant compared group-I with group-II)

Group I – Only gauze is placed in extraction socket

Group II – Feracrylum coated gauze is placed in extraction socket

Table-4: Comparison of mean bleeding time values between the groups at 5 min



Group I – Only gauze is placed in extraction socket

Group II – Feracrylum coated gauze is placed in extraction socket

In comparison of mean bleeding time at 5 minutes feracrylum is statistically significant with the standard gauze

Table-5: Comparison of mean bleeding time values between the groups at different time periods

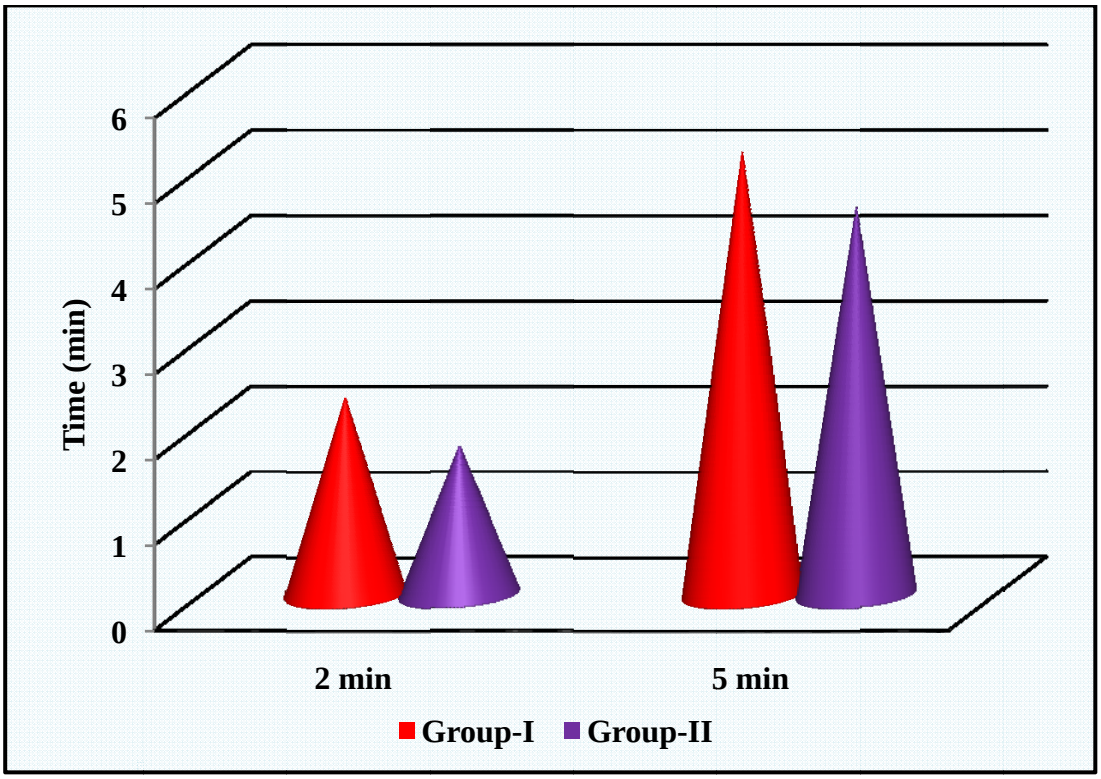
Groups	Bleeding time (min) (MEAN±SD)	
	2 min	**5 min**
Group-I	2.30±0.01	5.18±0.38
Group-II	1.72±0.46*	4.53±0.52*

(*P<0.05 significant compared group-I with group-II)

Group I – Only gauze is placed in extraction socket

Group II – Feracrylum coated gauze is placed in extraction socket

Graph-5: Comparison of mean bleeding time values between the groups at different time periods



Group I – Only gauze is placed in extraction socket

Group II – Feracrylum coated gauze is placed in extraction socket

In comparison between mean bleeding time between groups at different time periods, feracrylum is statistically significant with the standard gauze

Discussion

Tissue repair, inflammation and blood coagulation are closely related for required healing to occur a biologically stable union between broken tissues. The clotting factors intiate reparative changes. For healthy process to occur both fibrin deposition and fibrinolysis are linked to healing process. In addition angiogenesis was induced by fibrin degradation products and produce a wide variety of biological actions. Bleeding in oral and maxillofacial surgery is due to variety of systemic and local factors. Further negligence after post extraction both from surgeons and patients leads to problems.

With local haemostatic measures several of the problems were relieved. Of these pressure pack, suturing the socket, adrenalin pack or acrylic splint covering the socket were used. But arrest of bleeding from capillaries is sometimes difficult by above said methods where drug can be used. Various newly found agents such as thrombin, fibrin are difficult to place in extraction socket particularly in wet conditions. These agents expensive and carry the risk of viral disease transmission. Post operative bleeding is a problem in maxillofacial surgeries. In most number of times compression leads to arrest of bleeding but there are also situations where it could not be controlled. The newer hemostatic agent applied on extraction sites were the tenaxamic acid mouthwash, fibrin glue, cyanoacrylate, thrombin, microfibrillar collagen and oxidized cellulose.

Management of post extraction bleeding control after dental extraction is an important factor for completion of extraction procedures. If adequate interest is not shown it would lead to various post extraction problems. There have been various cases leading to death reported after dental extraction due to procedures that were not followed after dental extraction. Reports of various dental

institutions states that there are more number of cases of dry socket and surgical site infection.

Feracrylum is a cheapest drug device for bleeding control in various parts of the body, it has been already used in humans for various purposes to control blood. It is used as post operative dressing wherever it is needed. It is used for dressings of burnsite and dressing of various types of wounds. It is used in hypospadias surgery, it is used for packing of abscess. It is used in post operative packing in epistaxis and submucous resection of nasal septum and used in oral cavity.

The newest discovery in polymer research are the biodegradable and biocompatible polymers. On application exert therapeutic action, degrade and decompose in the body and are excreted out without causing toxicity or leaving toxic remnants in the body.

Feracrylum used in this research is biocompatible and biodegradable. When this gel comes in contact with serum proteins, it forms a whitish thin film form adduct gel like structure, which creates a physical barrier. This reduces bleeding from wound site and thus exerts hemostatic action.

In table 1 in comparison of continuous bleeding between group1 and group 2. In group 1 all the persons were bleeding after two minutes and 70% of case at 5 minutes.

In group 2, with hemostatic agent coated gauze only 60% of cases is bleeding at 2 minutes whereas seven cases were bleeding at 5 minutes.

In table 2 between comparison of mean cessation of bleeding values between groups. Group 1 values -9.54 ±1.89 and group 2 -6.65±0.96. There is statistically significant difference between group1 and group2.

In table 3 comparison of mean bleeding time values between two groups at 2 minutes there was a statistically significant values between two groups.

In table 4 comparison of mean bleeding time between values between groups 1 and group 2 at 5 minutes there was a statistically significant difference between groups. Group1 values 5.18±0.38 and group 2 values 4.53±0.52.

In table 5 comparison of mean bleeding time values between groups at different times period (at 2 minutes and at 5 minutes), there was a statistically significant difference between group 1 and group2.

As per the hemostatic property of the drug, feracrylum provides the ideal choice for patients after post extraction bleeding control. No reported case of post operative follow ups regarding dry socket or any surgical site infection after feracrylum was noted. This also denotes the antimicrobial and antibacterial nature of drug.

It also not absorbed in the systemic circulation due to its high molecular weight (more than 1,00,000 daltons) and hence it is not likely to affect the functions of kidney, liver, adrenal glands, cardiovascular system, haemopoetic and nervous system.

Although feracrylum is highly superior than standard gauze, the properties of standard gauze in controlling the flow of blood is acceptable. It is the best choice for patients undergoing dental extraction traditionally.

But for cases that have been seen in government hospitals and primary health centers where large number of cases were reported for extraction and only limited facilities for teeth restorative procedures is available and for the subjects with low economic conditions, feracrylum is the best drug device regarding postoperative wound healing and also early and easily disposal of cases. Clot stabilization is also of satisfactory level in feracrylum administration of drugs.

So the ideal haemostatic agent which satisfies arrest of bleeding, antibacterial and antifungal, antihygroscopic, better handling property with no systemic absorption along with better cost benefit and risk benefit ratios is Feracrylum. This drug is approved in market and by Central Drug Standard Control Organization (CDSCO).

It is very much useful in cosmopolitan and rural dentistry practice, (ie. PHC)

Summary

This study was done to evaluate the post-extraction bleeding control by Feracrylum (haemostatic agent) coated gauze versus standard gauze in dental extraction cases.

Each patient has a minimum of two therapeutic extraction referred from the department of orthodontics either in the same jaw or between one extracted teeth in one jaw and other in lower jaw.

The first extracted teeth is group II where feracrylum haemostatic agent coated gauze is placed in extraction socket and the patient is asked to bite the gauze and the bleeding level is noted in two minutes and at 5 minutes

The second extracted teeth is group I where standard dental gauze of 10 x 10c ms is placed in extraction socket and similarly the patient is asked to bite the gauze and the bleeding level is noted in two minutes and at 5 minutes.

In this study, feracrylum coated gauze is statistically significant over standard gauze in terms of post-extraction bleeding control in dental extraction cases.

All cases were reviewed after three days after extraction.

No cases reports of any complaints

Feracrylum also shows properties of antibacterial, antifungal, anti-hygroscopic along with cost benefit and risk benefit ratios

This also needs further research.

Conclusion

Within the limits of the study, the following conclusion were drawn

- Feracrylum is a haemostatic medical drug device that controls blood faster than standard dental gauze of (10x10cm) in dental extraction cases.
- Standard dental gauze of (10x10 cm) also controls blood loss but it absorbs blood. It absorbs about 3-3.5ml of blood per gauze piece.[7]
- Feracrylum coated gauze does not absorb blood. It effectively acts as a barrier.
- It forms clot stabilization to occur in order for better post-extraction wound healing after extractions.
- Due to its (Feracrylum) high molecular weight, it has not systemic absorption.
- It also has antibacterial, antifungal and ant hygroscopic phenomenon.
- It has a better handling properly.
- This drug device (Feracrylum) is suitable for dental extraction type of surgery.
- It has merits of both risk-benefit and cost benefit ratios.
- The most suitable way to control blood after dental extraction is gauze coated with feracrylum gel.

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Appendix

CONSENT FORM

PART 2 OF 2

PARTICIPANTS CONSENT FORM

The details of the study have been explained to me in writing and the details have been fully explained to me. I am aware that the results of the study may not be directly beneficial to me and at sometimes it will be beneficial but will help in the advancement of medical sciences. I confirm that I have understood the study and had the opportunity to ask questions. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without the medical care that will normally be provided by the hospital being affected. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). I have been given an information sheet giving details of the study. I fully consent to participate in the study titled

"Evaluation of Post-extraction bleeding control by haemostatic agent coated Gauze versus standard gauze in dental extraction cases. An Invivo study"

Serial No / Reference No :

Name of the participant :

Address of the Participant :

Contact number of the Participant :

Signature / Thumb impression of the participant / Legal guardian :

Witnesses :

1.

2.

Date :

Place :

பாகம் 2

பங்கு பெறுபவரின் ஒப்புதல் படிவம்

இந்த குறிப்பை பற்றி எனக்கு கற்பிக்கப்பட்டுள்ளது. அதன் ஒரு நகலும் எனக்கு தரப்பட்டுள்ளது. இந்த குறிப்பு முழுக்க முழுக்க அறிவியல் சம்பந்தப்பட்டது. ஆனால் தங்களுக்கு இதிலிருந்து எந்தவித லாபகரமும் இல்லை. இந்த அறிவியல் படைப்பின் கோட்பாடுகள் அனைத்தும் எனக்கு விளக்கித் தரப்பட்டுள்ளது. மற்றும் இதில் எழும் அனைத்து சந்தேகங்களும் எனக்கு விளக்கித் தரப்பட்டுள்ளது. இதில் எனக்கு பங்கு பெறவும், விலகவும் எனக்கு அவகாசம் உண்டு என்று புரிந்து கொள்கிறேன். இதனால் எனது மற்ற சிகிட்சைகளுக்கு எந்த தடங்கலும் நேரிடாது என்று அறிவித்துக் கொள்கிறேன்.

இந்த ஆராய்ச்சியின் குறிக்கோள் “பல் எடுத்த பிறகு பல் எடுத்த இடத்தில் இரத்தம் கட்டுப்படுத்தும் மருந்தினை தடவிய துணி மற்றும் (வழக்கமாக) எப்பொழுதும் பயன்படுத்தும் (இரத்தம் கட்டப்படுத்தும்) துணியை கொண்டு நோயாளிகளின் பிரிவுகளின் கீழ் வைத்து, ஒப்பிடு செய்து இரத்தம் உறையும் தன்மையை அறிந்துகொள்வது”

குறிப்பு எண் :

பெயர் :

முகவரி :

தொலைபேசி எண் :

கையொப்பம்

சாட்சி : 1.

2.

സമ്മതപത്രം

ഭാഗം- 2

ഈ പഠനത്തെ പറ്റിയുള്ള എല്ലാ കാര്യങ്ങളും എനിക്ക് പറഞ്ഞ് മനസ്സിലാക്കി തരികയും അതിന്റെ ഒരു പകർപ്പ് എനിക്കു നൽകുകയും ചെയ്തിട്ടുണ്ട്. ഈ പഠനം ഗവേഷണത്തിനായി ഉള്ളതാണെന്നും എനിക്ക് ഇതിൽ നിന്ന് നേരിട്ട് ഒരു ഫലവും ഉണ്ടാകില്ലെന്നും ഞാൻ മനസ്സിലാക്കുന്നു. ഈ പഠനത്തിന്റെ രീതിയും ഉദ്ദേശവും എനിക്ക് മനസ്സിലാക്കി തന്നിട്ടുണ്ട്. അതു പോലെ എനിക്ക് സംശയങ്ങൾ ചോദിക്കാൻ അവസരങ്ങൾ ലഭിച്ചിട്ടുമുണ്ട്. ഇതിൽ പങ്കെടുക്കാനും പങ്കെടുക്കാതിരിക്കാനും ഉള്ള അവകാശം എനിക്കുണ്ടെന്നും അതുപോലെ പഠനത്തിന്റെ ഏതു ഘട്ടത്തിലും ഇതിൽ നിന്ന് പിൻവങ്ങാനുള്ള സ്വാതന്ത്ര്യവും എനിക്കുണ്ടെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു. ഈ പഠനത്തിൽ പങ്കെടുക്കുന്നതുകൊണ്ടോ, പങ്കെടുക്കാത്തതുകൊണ്ടോ എന്റെ മറ്റു ചികിത്സകളെ ബാധിക്കുന്നതല്ലെന്ന് ഞാൻ അിറയുന്നു.

"ഈ പരീക്ഷണത്തിന്റെ ഉദ്ദേശം ശസ്ത്രക്രിയ മുഖേന പല്ലെടുക്കുമ്പൾ രക്തത്തെ നിയന്ത്രിക്കുന്ന മരുന്നിനെ തടവിയ തുണി മറ്റും ഉപ്പു തടവിയ മുക്കിയ തുണികൊണ്ട് രക്തം ഉറയിക്കുന്ന വിധത്തെ അറിയുന്നത്." എന്നഗവേഷണത്തിൽ പങ്കെടുക്കുന്നതിനും ഇതിന്റെ ഫലങ്ങൾ ശാസ്ത്രലേഖനത്തിൽ പ്രസിദ്ധീകരിക്കുന്നതിനും എനിക്ക് സമ്മതമാണെന്ന് ഞാൻ ഇതിനാൽ അിറയിച്ചുകൊള്ളുന്നു.

സീരിയൽ നമ്പർ / റഫറൻസ് നമ്പർ :

പങ്കെടുക്കുന്ന ആളിന്റെ പേര് :

മേൽവിലാസം :

ഫോൺ നമ്പർ :

ഒപ്പ് / വിരലടയാളം

സാക്ഷി :

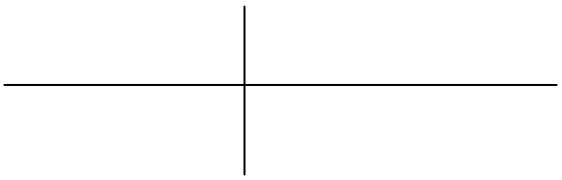
സ്ഥലം :

തീയതി

DATA SHEET FORM

ID No :

Tooth On Which Procedure is Done :



Group : A B

I

Duration of Active Bleeding	At 2 minutes	At minutes

II

Continuous bleeding	Yes	No

III

Cessation of Bleeding	Yes	No

Signature of Observer ***Signature of Investigator***

SREE MOOKAMBIKA INSTITUTE OF DENTAL SCIENCES

KULASEKHARAM, KANYAKUMARI DIST., TAMIL NADU, INDIA.

INSTITUTIONAL RESEARCH COMMITTEE

Certificate

This is to certify that the research project protocol, ***Ref no. 01/08/2014*** titled, ***"Evaluation of post-extraction bleeding control by haemostatic agent coated gauze versus standard gauze in dental extraction cases – An invivo study"*** submitted by ***Dr. Thinakar Babu, III Year MDS, Department of Oral and Maxillofacial Surgery*** has been approved by the Institutional Research Committee at its meeting held on 14th ***August 2014.***

Convener
Dr. T. Sreelal

Secretary
Dr. Anuroopa A.

ETHICA NORMA

Dr. V.VIJAYALAKSHMI, M.B.B.S,
(Chairperson)
19/11, Gandhi street, Vanuampet,
Chennai 600091
Email: foryou.venkar@gmail.com

ECR/154/Indt/TN/2014 **Date: 26/11/2014**

To,

Dr. A. THINAKAR BABU M.D.S., (Oral & Maxillofacial Surgery)
Principal Investigator
Department of Oral & Maxillofacial Surgery,
Sree Mookambika Institute of Dental Science, Kulasekharam.
Mobile No.: +91-9941829842
Email: thinakar_drbabu@yahoo.co.in

Dear Dr. Thinakar Babu,

"Ethica Norma" Ethical Committee reviewed and discussed your application to conduct the bioequivalence study entitled **"EVALUATION OF POST-EXTRACTION BLEEDING CONTROL BY HEMOSTATIC AGENT COATED GAUZE VERSUS STANDARD GAUZE IN DENTAL EXTRACTION CASES – AN INVIVO STUDY"**

The following documents were reviewed:

a. Study Protocol, dated 21/07/2014.
b. Patient Information Sheet or Informed Consent form (including updates if any) in English and/or vernacular language (Tamil).
c. Principal Investigator's current CV.

The quorum of the ethics committee was present in the meeting held on 26/11/2014 at 04:00 PM at CHEMECH LABORATORIES, KK NAGAR, CHENNAI.

We approve / ~~do not approve / recommend for revision of~~ - the documents / protocol to be conducted in its presented form.

26/11/14

Chairperson,
Dr. V. Vijayalakshmi - Ethics Committee.

The Ethics committee expects to be informed about the changes in the documents/progress of the study, any adverse events occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.